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Evaluation of Vibradiofotology Technology using the ERECTOFIX Device in the Treatment of Erectile Dysfunction: A Randomized Controlled Double-Blind Pilot Study

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Abstract

Introduction: Over the past decade, energy-based therapies have been introduced as non-invasive and restorative treatment modalities for erectile dysfunction. Furthermore, previous studies have shown the efficacy of penile vibratory stimulation and photobiomodulation in treating erectile dysfunction. Integrating these therapeutic approaches, which are employed simultaneously in the Vibradiofotology technology, may lead to achieving better outcomes in the treatment of erectile dysfunction. This study aims to evaluate the efficacy of Vibradiofotology technology delivered via the Erectofix device in patients with erectile dysfunction.

Methods: In this randomized clinical trial, fifty-five patients diagnosed with erectile dysfunction were included. The patients were assigned to either the control group or the intervention group. In the intervention group, the patients received treatment with the Erectofix device for five sessions. Each session lasted 45 minutes and was administered once a week. Meanwhile, the control group received oral medication along with sham laser treatment.

Results: Among the fifty-five patients included in the study, 27 were assigned to the intervention group and 28 to the control group. The intervention group showed a significant improvement in each domain of the IIEF score compared to the control group. The erectile function showed a significantly greater increase in IIEF scores in the intervention group (19.59 ± 5.57) compared to the control group (7.39 ± 2.23; $P < 0.001$). Furthermore, significant improvements were observed in orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction in the intervention group.

Conclusion: Vibradiofotology technology, which integrates different therapeutic approaches, may be a safe treatment option for erectile dysfunction. Improvements in IIEF scores, patients' overall satisfaction, and erectile function can be promising in the efficacy of this modality. Nevertheless, due to the limitations of the present study, further research is required to investigate the potential benefits of this novel modality in improving patients' quality of life.

Keywords: Erectile dysfunction, Photobiomodulation, Radiofrequency therapy, Restorative therapy, Vibration

Introduction

Erectile dysfunction (ED) is defined as an abnormality in achieving or maintaining an erection, which can impact sexual satisfaction.[1] ED can significantly impact patients' overall quality of life, and various factors, including vascular, hormonal, and neurological causes, can contribute to its pathogenesis.[2,3] Hence, treatment options may vary based on the underlying cause and individual needs. PDE5 inhibitors and intracavernosal injections are considered first-line treatments for ED.[4] However, due to treatment failure or intolerable adverse effects in some patients, there has been growing attention to the development of alternative or adjunctive treatments. Recently, energy-based modalities have demonstrated positive effects in the treatment of ED.[5,6] Low-intensity shockwave therapy (ESWT-LI) has shown promising results for treating ED.[7] Nevertheless, an approach that targets multiple key pathways involved in ED may have synergistic effects beyond conventional treatments.

The energy-based modalities stimulate biological processes that promote tissue repair by releasing growth factors, inducing neovascularization, enhancing endothelial function, and remodeling the extracellular matrix.[8] One of the emerging energy-based treatment modalities is the Vibradiofotology technology (ErectoFix®), which has been applied to a wide range of genitourinary conditions.

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This technology combines photobiomodulation (630 nm), low-energy radiofrequency, and penile vibratory stimulation (PVS) to achieve its therapeutic effect. This combination may yield greater improvements in erectile function compared to employing any modality alone.

Previous studies have reported that PVS is an FDA-approved technique for ED treatment that increases penile blood flow and stimulates angiogenesis in the genital capillaries. Moreover, the efficacy of photobiomodulation therapy (PBMT) at a 630-nm wavelength for restoring erectile function has been supported by some research. PBMT exerts its effects by stimulating nerve sprouting and angiogenesis.[9] Regarding the efficacy of radiofrequency energy, multiple pilot studies have shown considerable improvements in validated ED measures. This treatment approach targets collagen structures and thereby elicits its effects.

Employing the combination of these energy technologies as a safe and effective option for ED, without any significant side effects, may improve overall outcomes in these patients.[10]

Nonetheless, clinical research on the efficacy and safety of the Vibradiofotology technology for the treatment of ED remains limited. Lack of data on the potential synergistic effects of combining these energy-based modalities, along with the small sample sizes of previous studies, highlights the need for further investigation. Therefore, the goal of this study is to evaluate the accuracy and effectiveness of the Vibradiofotology technology using the Erectofix device in treating ED.

Method

Study Design

This double-blind, randomized clinical trial study was conducted between August 2022 and 2024.

The participants in the study adhered to all Helsinki ethical principles. All patient information remained confidential and was not disclosed to any individual or legal entity. Participation in the research did not impose any financial burden on the participants. Finally, written informed consent was obtained from the participants.

Patient Selection

The target population consisted of men aged 30 to 55 with mild erectile dysfunction, according to the IIEF-15 questionnaire, and they were referred to the urology clinic at Shohada Tajrish Medical Center, Tehran, Iran. All individuals referred to the clinic were examined until the predetermined sample size was achieved. They were evaluated based on the defined inclusion criteria for enrollment in the study. The exclusion criteria were as follows: a history of major cardiovascular disorders, such as recent myocardial infarction, stroke, uncontrolled hypertension, or congestive heart failure; a history of severe psychiatric disorder, such as severe depression; a history of uncontrolled metabolic disorders including diabetes, dyslipidemia, and thyroid disorders; a history of urological surgery or penile trauma causing arteriovenous fistula, neurological, or vascular defects; a history of substance abuse, including smoking and alcohol. Patients currently using medications that may affect erectile function, such as nitrates, alpha-blockers, anticoagulants, antipsychotics, benzodiazepines, and antiandrogens, were also excluded.

Intervention Protocol

In the intervention group, energy transfer was performed using PVS embedded in the Erectofix device (Medaria Company) for 45 minutes by a trained specialist. All patients in both groups received standard medications for ED under physician supervision. The intervention group underwent a 5-session course of treatment on a weekly basis. The control group received a sham treatment. In the sham procedure, the device light was turned on, but no therapeutic energy was applied.

The treatment protocol consisted of two phases in each session. In phase one, pelvic activation was performed by applying adhesive electrodes to the lower abdomen and lower back. This was followed by 20 minutes of multi-wavelength thermal radiofrequency (RF) delivery. This phase aimed to enhance pelvic blood flow, lymphatic drainage, deep detoxification, and oxygenation of pelvic tissues. In phase two of this intervention, the Erectile Active Applicator was applied with ultrasound gel for penile rejuvenation. The penile shaft was enclosed between two electrodes and treated with a combination of alternating monopolar and bipolar radiofrequency energy, vibro-percussion stimulation, and 630 nm LED therapy for 20 to 30 minutes. A return electrode remained on the lower back. The device software dynamically adjusted treatment duration based on energy absorption thresholds and patient comfort.

This device employs vibradiofotology, a therapeutic innovation aligned with FDA and CE standards. This technology combines soft contractile radiofrequency (500–1300 kHz), micromechanical vibro-percussion, and high-brightness diode emission (630 nm) to exert its therapeutic effect. The software used in this device adjusted energy parameters in real-time, measured total energy absorbed by tissues, and optimized treatment protocols based on tissue type and patient tolerance. This feature helped optimize treatment effectiveness and patient safety during the procedure.

Randomization and Allocation

Patients were randomly assigned to intervention and control groups by Microsoft Excel to generate random numbers, assigning even numbers to the intervention group and odd numbers to the control group. This process continued until the required sample size for

each group was reached. To ensure blinding, the control group received a sham laser treatment, and both groups were blinded to their group assignment. Furthermore, the assessor who gave the questionnaire was also blinded to participants' treatment allocation.

Sample Size

According to the pilot study results and considering $\alpha = 0.05$ and 80% power, the sample size was calculated by the formula to be about 27 patients in each group.

Outcome Measures

An accurate demographic, clinical history, and physical examination were recorded during the first visit.

To assess erectile function, the International Index of Erectile Function (IIEF-15) questionnaire was used. According to the IIEF-5 questionnaire, the classes of ED were identified as follows: severe (5-7), moderate (8-11), mild to moderate (12-16), mild (17-21), and normal (22-25).

Individuals in both groups filled out the 15-question IIEF International Erectile Function Index questionnaire before and three months after receiving the respective treatment.

The treatment goal was assessed by the feasibility of sexual intercourse via the IIEF-5 questionnaire. The occurrence of adverse effects of the laser was also investigated.

The required data were recorded on a checklist after evaluating the patients based on study variables, and other pieces of information were extracted from their files and completed in the same checklist.

Statistical Analysis

The biostatistician was blinded to treatment groups. SPSS (version 26 for Windows, SPSS Inc., Chicago, IL) is a statistical software package used for data analysis. A *P*-value less than 0.05 was considered statistically significant. Results were reported as mean ± SD. The normality of data was tested with the Shapiro-Wilks test. Comparison within groups was performed using a paired-samples t-test, while comparison between groups was carried out using an independent t-test. Missing data were completely at random; therefore, they were ignored.

Results

Fifty-five men were included in this study; twenty-seven (49.1%) patients were in the intervention group, and twenty-eight (50.9%) were in the control group. The allocation of the patients to the intervention and control groups during the study is illustrated in Figure 1. All enrolled patients completed the study, and no dropouts or

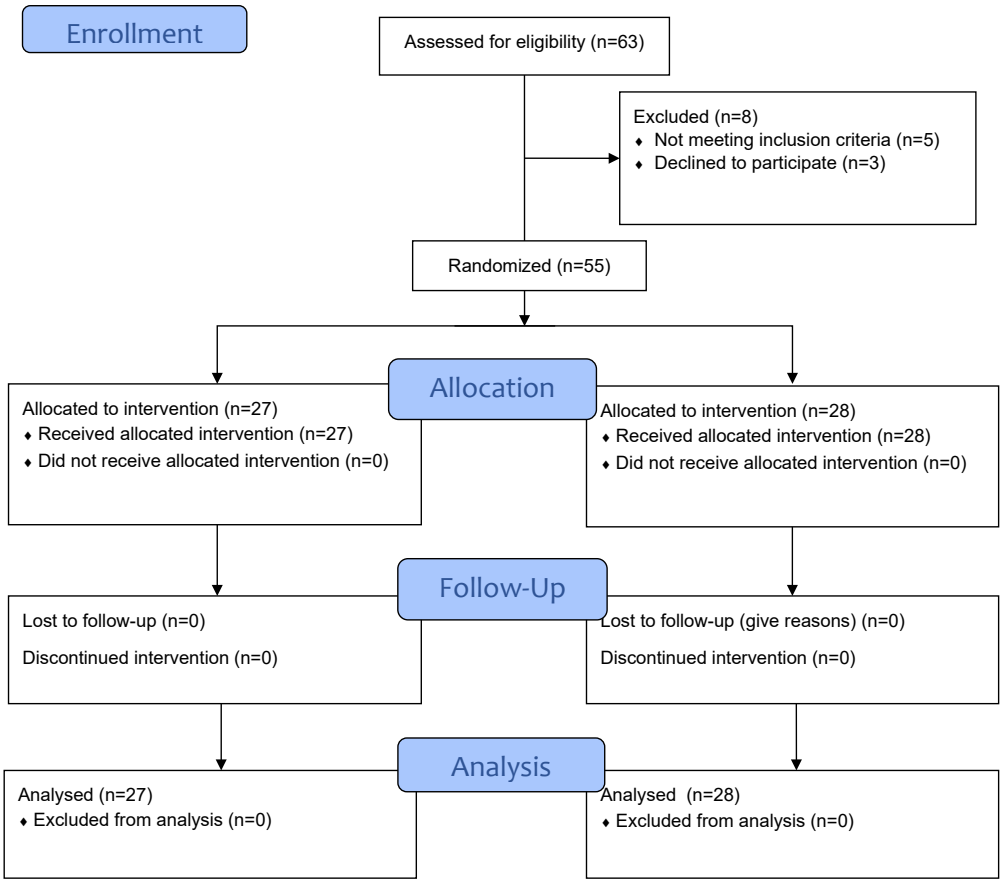

Figure 1. Consort flow chart

losses to follow-up occurred during the study.

At baseline, both groups were matched in terms of demographic and clinical characteristics (Table 1). The mean of the IIEF domain score questionnaire before and after the study and their changes are shown in Table 2. In each domain, the increasing score in the intervention group was statistically more significant than that in the control group. The mean of the IIEF score at baseline was 28.74 ± 7.95 in the intervention group, and it was 29.68 ± 8.49 in the control group (*P*-value = 0.674). After the study, these scores were 48.33 ± 8.70 and 37.07 ± 8.11 in the intervention and control groups, respectively (*P*-value = 0.0001). The increase of the IEEF score in the intervention group was 19.59 ± 5.57, and in the control group, it was 7.39 ± 2.23 (*P*-value < 0.001). Throughout this study, the patients were monitored for adverse events. At each session, the patients were questioned about any potential side effects. Only two patients in the intervention group experienced transient pruritus, which is classified as grade 1 in severity based on CTCAE criteria. The symptoms were mild and self-limited, and resolved without intervention.

Discussion

ED, as one of the most common male sexual disorders worldwide, can significantly impair patients' quality of life.

Table 1. Comparison of the background characteristics of the patients of the two groups

Patients Characteristics	Intervention group (n = 27)	Control Group (n = 28)	*P*-value
Age	34.61 ± 5.18	35.28 ± 5.78	0.646
BMI	27.13 ± 4.75	28.32 ± 5.14	0.375
Smoking	8(29.60%)	6(21.42%)	0.490
History of Ed (month)	2.31 ± 1.02	1.85 ± 0.79	0.066
Diabetes Mellitus	5(18.52%)	6(21.42%)	0.787
Hypertension	4(14.28%)	3(10.71%)	0.648
Hyperlipidemia	8(29.63%)	6(21.42%)	0.48

Treatment strategies may vary based on disease severity and patient preference, including the management of underlying conditions to oral medications, penile injections, and energy-based therapies. Inadequate response to oral or injected medications has led to evolving energy-based therapies, such as low-intensity shock wave therapy, radiofrequency energy (ESWT-LI), and vibratory stimulation, to achieve a better outcome. Clinical evidence supports the efficacy of ESWT-LI in improving ED, with a significant increase in the IIEF score and in the Erection Hardness Score (EHS), compared to sham therapies.[11] In addition, a recent pilot study showed that radiofrequency energy-based treatment can be a safe and promising modality for the treatment of ED [12]. Other studies demonstrated that vibratory stimulation and vacuum erection of the penis have positive effects in the treatment of this disease. While previous studies support the efficacy of ESWT-LI, findings on the efficacy and safety of integrating energy-based modalities are limited. Hence, this study aimed to determine whether using Vibradiofotology technology, which combines photobiomodulation, radiofrequency energy, and vibratory stimulation, can enhance erectile function in patients with ED compared to the control group.

Our results showed that patients treated with the Erectofix device had higher IIEF scores in all domains compared to the control group. These improvements suggest that combining energy-based therapies may positively affect erectile function, orgasmic function, sexual desire, and intercourse satisfaction (Table 2). These results could indicate the synergistic effects of these energy-based modalities, which target neurogenic and vascular components of ED. Photobiomodulation promotes nerve repair and angiogenesis by enhancing mitochondrial function, stimulating cellular metabolism, and upregulating growth factors.[13] Furthermore, the vibratory stimulation of penile tissue activates neurostimulatory pathways by triggering the cavernous nerves.[14] This results in the release of nitric oxide and improves penile blood

Table 2. Mean of the IIEF domain score in each group

	Intervention group			Control group			*P*-value (mean difference)
	Before	After	*P*-value	Before	After	*P*-value	
Erectile Function	9.83 ± 3.09	16.10 ± 3.37	< 0.001	9.86 ± 3.21	11.93 ± 3.16	< 0.001	
	6.59 ± 1.91			2.07 ± 0.66			< 0.001
Orgasmic Function	4.40 ± 1.69	7.40 ± 1.22	< 0.001	4.39 ± 1.77	5.50 ± 1.55	< 0.001	
	3.19 ± 1.07			1.11 ± 0.63			< 0.001
Sexual Desire	5.03 ± 1.35	7.83 ± 1.28	< 0.001	5.00 ± 1.33	6.04 ± 1.35	< 0.001	
	2.89 ± 1.12			1.04 ± 0.51			< 0.001
Intercourse Satisfaction	5.83 ± 1.44	9.77 ± 2.03	< 0.001	5.86 ± 1.43	8.07 ± 1.74	< 0.001	
	4.15 ± 1.68			2.21 ± 1.34			< 0.001
Overall Satisfaction	4.43 ± 1.45	7.47 ± 1.61	< 0.001	4.46 ± 1.50	5.68 ± 1.74	< 0.001	
	3.19 ± 1.11			1.21 ± 0.87			< 0.001

flow.[15] Moreover, the radiofrequency energy induces collagen fiber remodeling and restoration in penile tissue, which is crucial for erectile function.[12] The role of collagen fibers in increasing the intracavernosal pressure and their integration with elastin to compress the emissary veins highlights their importance in achieving and maintaining an erection.

The results of prior studies are consistent with the findings observed in this study. Rullo et al[15] suggested that vibratory stimulation can effectively improve overall sexual function by treating erectile dysfunction, anorgasmia, and ejaculatory dysfunction by employing a neurostimulatory pathway. Another evidence-based literature introduced the vibratory stimulation and vacuum erection techniques as a safe and non-invasive option for ED patients.[16] Furthermore, Fode et al[17] evaluated the effect of penile vibratory stimulation on the erection and urinary continence following prostatectomy. Their results showed a trend towards better erectile function in the intervention group; however, the IIEF scores were not significantly different between the control and intervention groups.

Additionally, photobiomodulation therapy has demonstrated promising efficacy in treating ED, particularly in patients with nerve injury or vascular impairment. A recent study in murine models reported that the utilization of PBMT can restore erectile function in models with cavernous nerve injury.[9] Moreover, Zheng et al[13] demonstrated that repeated near-infrared PBMT can improve erectile function, enhance endothelial function, and reverse pathological remodeling in mice with age-related ED. Thus, PBMT can play a role in the treatment of ED by stimulating angiogenesis and enhancing nerve repair.

Clinically, this non-invasive treatment modality, which employs the combination of vibratory stimulation, photobiomodulation, and radiofrequency, can be a safe option in patients with inadequate response to oral or injectable medications. While conventional pharmacotherapy typically targets a single component of ED pathophysiology, employing these treatment strategies that target multiple pathways may yield better outcomes.

During the study period, no adverse events were reported. Only two patients experienced transient pruritus. These symptoms were mild and self-limited, and they were classified as grade 1 in severity based on the CTCAE guideline.

This study has some limitations that should be considered. The small sample size and short-term follow-up are the key limitations. To draw more accurate conclusions, further research with a multicenter population, larger sample sizes, and extended follow-up periods is warranted. Moreover, excluding patients with a history of diabetes, hypertension, and smoking, which are common risk factors for ED, limits the generalizability of these findings. Additionally, this study was conducted in a specific population with certain demographic and cultural characteristics. Conducting similar research in diverse populations is necessary to achieve more accurate and applicable results. Finally, this treatment modality requires a trained specialist, which may limit the applicability of this device in routine clinical settings.

Conclusion

To the best of our knowledge, this is the first study which has investigated the safety and effectiveness of Vibradiofotology technology. In this technology, the combination of vibratory stimulation, radiofrequency, and photobiomodulation is utilized for the treatment of ED. As a non-invasive therapeutic option, this treatment strategy targets neurovascular components involved in the pathophysiology of ED. This integration may be more effective than employing either modality alone. Our preliminary findings are promising, but further clinical trials with larger sample sizes and extended follow-ups are necessary to fully demonstrate its efficacy.

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Authors' Contribution

Conceptualization: Mohammadreza Razzaghi.
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Writing–review & editing: Morteza Fallah karkan, Parnia Rahnamay Farnood.

Competing Interests

The authors declare that they have no competing interests.

Ethical Approval

The study protocol was registered with the Iranian Registry of Clinical Trial (ID: IRCT20111121008146N40) and approved by the Authority Research Ethics Board at Shahid Beheshti University of Medical Sciences (IR.SBMU.RETECH.REC.1401.106).

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